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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,152	11/13/2003	Sekhar Boddupalli	0113-UTL2	2364

7590 03/24/2009

Gloria Pfister
Galileo Pharmaceuticals, Inc.
5301 Patrick Henry Dr.
Santa Clara, CA 95054

EXAMINER	
QAZI, SABIHA NAIM	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/714,152	BODDUPALLI ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/14./04,11/13/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Non-Final Office Action

Claims 1-22 are pending. No claim is allowed at this time.

Summary of this Office Action dated 3/7/2009

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 (1) Written Description Rejection
5. Response to Remarks
6. Communication

Examination of claims for purposes other than application of prior art, e.g. rejections under 35 USC 112, first and second paragraphs, will be understood to be made in the interest of completeness of prosecution and should not be considered as indicating that search has been extended to non-elected species.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Copending Applications

Applicants must bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications, which are "material to patentability" of the application in question. MPEP 2001.06(b). See Dayco Products Inc. v. Total Containment Inc., 66 USPQ2d 1801 (CA FC 2003).

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112—Written Description Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. Following reasons apply. Following reasons apply:

Specification discloses in example s 1-5 use of oxazolone from Sigma chemical company. There is no data, teaching or guidance how to make and use the claimed invention. The specification does not contain the written description of the claimed subject matter.

Claims are drawn to a method of reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition containing the compound of formula I. In formula I R can be O, S, SO, SO2, a secondary or tertiary amine , a phosphate, a phosphor-ester, or a substituted or unsubstituted methylene group. These compounds include thousands of compounds. See also when n can be 0 to 3, so that the hetero ring will vary depending on n.

Applicant had no possession at the time this application was filed of claimed subject matter. The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to one skilled in the art that the inventor had the possession at the time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claimed language.

See In re Kaslow, 707 F 2d 1366, 1375 (Fed. Cir. 1983).

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., In re Wilder, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "reducing the level of CRP and CRP associated condition" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material

> does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See Univ. of Calf. V. Eli Lilly, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation

between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.

Here, the specification does not provide a reasonably representative disclosure of useful for reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions.

Applicant is kindly requested to explain the issue. In the present case Applicant has no possession for the claimed subject matter. Further the compounds as in claim 1 covers large number of compounds to treat cancer. At the time invention was filed applicant has no possession of the invention as claimed.

The written description requirement prevents applications from using the amendment process to update the disclosure in their disclosures (claims or specification) during the pendency before the patent office. Otherwise applicants could add new matter to their disclosures and date them back to their original filing date, thus defeating an accurate accounting of the priority of the invention. See 35

USC 132. The function of description requirement is to ensure that the inventor had possession, as of filing date of the application relied on, the specific subject matter claimed by him.

See *Genetech,* 108 F 3d 1361, 1365 (Fed. Cir. at 1366, 78, 1999).

Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406; *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

See MPEP 2163.06.

Response to Remarks

Applicant's response filed on 11/18/2008 with traverse the election of species when R is O is hereby acknowledged.. It is unclear that Applicant cites election of claim 2 from group 2 because there are no groups. The request was for

the election one species. Applicant should have elected one compound from claim 2. The basis of the traversal is that Applicants consider that there is no undue burden to examine all the claimed invention. Claims are drawn to a method of reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition containing the compound of formula I. In formula I R can be O, S, SO, SO2, a secondary or tertiary amine, a phosphate, a phosphor-ester, or a substituted or unsubstituted methylene group. These compounds include thousands of compounds. Furthermore, n can be 0 to 3, so that the hetero ring will vary depending on n.

Examiner disagrees because the compounds of formula I as in claim 1 contain large number references as was evidenced by the search on STN. It is not possible to go through all the references to determine the patentability of invention. It will be an undue burden on the examiner to examine all the invention as has been claimed. For the same reasons restriction is maintained and is made final.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571)

272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612

Notice of References Cited	Application/Control No. 10/714,152	Applicant(s)/Patent Under Reexamination BODDUPALLI ET AL.	
	Examiner Sabiha Qazi	Art Unit 1612	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,699,860	03-2004	Ladouceur et al.	514/233.5
*	B	US-5,510,366	04-1996	Kyotani et al.	514/411
*	C	US-6,150,402	11-2000	Wechter et al.	514/458
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
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*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/714,152
Filing Date	11/13/2003
First Named Inventor	Boddupalli, Sekhar
Art Unit	
Examiner Name	
Attorney Docket Number	0113-UTL-02

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/S.Q./	A1	US- 5,747,528	05-05-1998	Trivedi, B.K.	
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature	/Sabiha Qazi/	Date Considered	03/06/2009

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 2

Complete if Known	
Application Number	
Filing Date	November 13, 2002
First Named Inventor	Boddupalli
Art Unit	
Examiner Name	
Attorney Docket Number	113-UTL2

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US- 6,150,402	11-21-02	Wechter J.et al.	
	2	US- 6,048,891	04-11-00	Wechter J.	
	3	US- 6,242,479	06-05-01	Wechter J.	
	4	US- 6,410,589	06-25-02	Wechter J.	
	5	US- 6,174,864	01-16-01	Yoshikawa et al.	
	6	US- 2001/0031782 A1	10-18-01	Wechter J.	
	7	US- 2003/0100603 A1	08-21-01	Beinlich P. et al.	
	8	US- 2003/0144219 A1	07-31-03	Phinney S. et al.	
	9	US- 4,452,801	06-05-84	Sundeen J	
	10	US- 4,360,532	11-23-82	Sundeen J	
	11	US- 4,321,270	03-23-82	Sundeen J	
	12	US- 6,051,586	04-18-00	Ladouceur, G et al.	
	13	US- 6,469,031	10-22-02	Connell R. et al	
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FOREIGN PATENT DOCUMENTS

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Examiner Signature	/Sabiha Qazi/	Date Considered	03/06/2009

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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.Q./

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	
Filing Date	November 13, 2003
First Named Inventor	Boddupalli, S et al.
Art Unit	
Examiner Name	
Attorney Docket Number	0113-UTL2

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	B1	SHIELDS, A. , 2000, "UTS study shows vit. E reduces levels of a protein that predicts heart disease". Press Release http://irweb.swmed.edu/newspub/newsdetl.asp?story_id=265	
	B2	RALOFF, J, 2000. "Vitamin E targets dangerous inflammation", Science News 158(11):311	
	B3	UPRITCHARD, JE et al., "Effect of Supplementation with...Vit E...on products of inflamm. activity in type 2 Diabetes", Diabetes Care, 23,6 :733-738	
	B4	PATRICK, L et al., "Cardiovascular Disease: C-reactive protein and the Inflammatory Disease Paradigm", 2001, Alternative Medicine Review, 6,:248-271	
	B5	HIMMELFARB J et al., "Alpha and gamma tocopherol metabolism in healthy patients with end-stage disease", 2003, Kidney International 64 (3) 978-	

Examiner Signature	/Sabiha Qazi/	Date Considered	03/06/2009

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